

AMENDMENTS TO THE CLAIMS

Please amend the claims so that they read as follows:

1. (Currently Amended) ~~An aqueous~~ A transmucosally delivered controlled release composition which upon administration exhibits substantially linear absorption rates, the composition comprising:

- (a) a therapeutically effective amount of morphine base monohydrate a ~~pharmaceutically active ingredient~~;
- (b) an effective amount of a controlled release chitosan polymer; and optionally comprising:
- (c) one or more antimicrobial agents;
- (d) one or more antioxidants; and
- (e) water;

wherein the molecule to molecule ratio of ~~the pharmaceutically active ingredient~~ morphine base monohydrate to the controlled release chitosan polymer ranges from about 1:1 to about 100,000:1 to provide substantially linear absorption rates upon administration.

2. (Currently Amended) The composition of claim 1, wherein the molecule to molecule ratio of ~~the pharmaceutically active ingredient~~ morphine base monohydrate to the controlled release chitosan polymer ranges from about 5,000:1 to about 80,000:1.

3. (Canceled)

4. (Currently Amended) The composition of claim 1 ~~claim 3~~, wherein the concentration of morphine base monohydrate is from about 18.75 mg/ml to about 300 mg/ml.

5. (Currently Amended) The composition of claim 1 ~~claim 3~~, wherein the concentration of morphine base monohydrate is from about 37.5 mg/ml to about 150 mg/ml.

6. (Currently Amended) The composition of claim 1 ~~claim 3~~, wherein morphine base monohydrate is purified morphine base monohydrate.

7. (Original) The composition of claim 1, wherein the concentration of the chitosan polymer is from about 2 mg/ml to about 7 mg/ml.

8. (Original) The composition of claim 1, wherein the concentration of the chitosan polymer is from about 4 mg/ml to about 6 mg/ml.

9. (Original) The composition of claim 1 wherein the antioxidant is selected from the group consisting of methanesulfonic acid, citric acid, sodium citrate, ascorbic acid, and sodium ascorbate.

10. (Original) The composition of claim 9, wherein the antioxidants are citric acid and sodium citrate, and the total amount of antioxidant is present in a range from about 20 to about 50% by weight/volume of the composition.

11. (Original) The composition of claim 9, wherein the antioxidants are ascorbic acid and sodium ascorbate, and the total amount of antioxidant is present in a range from about 40 to about 70% by weight/volume of the composition.

12. (Original) The composition of claim 9, wherein the antioxidant is methanesulfonic acid, and the amount of antioxidant is present in a range from about 10 to about 60% by weight/volume of the composition.

13. (Original) The composition of claim 1, wherein the antimicrobial agent is selected from the group consisting of benzalkonium chloride, disodium EDTA, sodium benzoate, and combinations thereof.

14. (Original) The composition of claim 12, wherein the concentration of antimicrobial agent is from about 0.0005% to about 0.5% by weight/volume of the composition.

15. (Currently Amended) The composition of claim 1 ~~claim 12~~, wherein the concentration of antimicrobial agent is from about 0.005% to about 0.5% by weight/volume of the composition.

16. (Original) The composition of claim 1, wherein the transmucosal delivery is selected from the group consisting of nasal, buccal, rectal, vaginal, and ocular modes of administration.

17. (Withdrawn) The composition of claim 1, wherein the transmucosal delivery is by nasal administration.

18. (Withdrawn) The composition of claim 1, wherein the composition is prepared under nitrogen gas by

(a) mixing the morphine and acid, polymer, and antimicrobial agents, wherein each ingredient is mixed into the solution for at least 5 minutes;

(b) adding the antioxidants, wherein the pH is from about 3.0 to about 5.0;

(c) adjusting the final batch volume with water to form a final solution; and

(d) filtering the solution with a pre-sterilized micron filter.

19. (Withdrawn) The composition of claim 18, wherein the pre-sterilized micron filter is about a 0.2 micron filter.

20. (Currently Amended) The composition of claim 1, wherein the composition yields about 18.75 to about 300 microgram of morphine base monohydrate ~~pharmaceutically effective agent~~ per 100 microliter nasal spray.

21. (Currently Amended) A method of administering ~~an aqueous~~ a controlled release ~~transmucosal morphine~~ medicament, wherein the medicament is administered transmucosally to a subject in need thereof, said medicament comprising:

- (a) a therapeutically effective amount of morphine base monohydrate a ~~pharmaceutically active ingredient~~;
- (b) an effective amount of a controlled release chitosan polymer; and optionally comprising:
- (c) one or more antimicrobial agents;
- (d) one or more antioxidants; and
- (e) water

wherein the molecule to molecule ratio of morphine base monohydrate to the controlled release chitosan polymer ranges from about 1:1 to about 100,000:1 to provide substantially linear absorption rates upon administration.

22. (Currently Amended) The method of claim 21, wherein the ~~pharmaceutically active ingredient~~ morphine base monohydrate is purified morphine base monohydrate.

23. (Original) The method of claim 21, wherein the subject is human.